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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,799	04/27/2000	Ai-Zhi Piao	T8275	2670

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/07/2003

61

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/559,799

Applicant(s)

PIAO ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 14-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt of Amendment A received on January 8, 2003 is acknowledged. Claims 1-13 are included in the prosecution of this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al (5,702,717) in view of EP 0092918.

Cha et al teach thermosensitive biodegradable polymers based on poly (ether-ester) block copolymers. The copolymer has a reverse gelation temperature and is made of a hydrophobic A polymer block such as poly (alpha-hydroxy acids) or poly (ethylene carbonates) and hydrophilic B polymer block of polyethylene glycol. See abstract. Instant poly (alpha-hydroxy acids) are taught on column 7, lines 39-55 with an average molecular weight between 500 to 10,000 Daltons. Block B has an average molecular weight between 1,000 to 20,000 Daltons. The block copolymer is a triblock copolymer, i.e. ABA or BAB. See column 7 in its entirety. Polymer block A makes up about 15-50% by weight of the copolymer and polymer B makes up about 50-85%. See column 12, lines 53-60. Cha teaches the controlled release of actives that corresponds to the biodegradation of the polymeric matrix. Cha teaches the use of the polymer matrix to release proteins at a controlled rate. See column 4, lines 40-46.

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Cha et al do not teach a mixture of two different copolymers.

EP teaches a continuous release formula of polypeptides for injectable hydrogel implants. See page 2, lines 60-63. The implant is made any pharmaceutically acceptable copolymer wherein polymer A is a hydrophobic polymer and B is a hydrophilic polymer of the formula ABA or BAB. See page 3, lines 25-31. The mechanism of release involves the swelling of the polymer when the polypeptide and copolymer are immersed in water. When equilibrium state has been reached the degradation of the hydrophobic region begins. The partially degraded copolymer has a greater swellability so that continued hydrolysis leads to progressive water uptake and further increase in polypeptide desorption which compensates for its decreasing concentration; thus maintaining its continuous release. The appropriate design of the copolymer material, the initial swelling of the hydrogel, and desorption of the active can be controlled to extend the release of the active. Further, by blending different copolymers, each having its own properties such as molecular weight, molecular weight distribution, block structure, hydrophilicity, degradation properties, and diffusion properties, the release rate and the duration of release can be varied. See page 4, lines 29-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look at EP and combine two polymers with different physical and chemical properties. One would be motivated to do so since EP teaches different copolymer blends allows for the variation of the release rate and duration of release of

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the active agent. Further since EP teaches a similar polymeric system, one of ordinary skill in the art would look at the guidance provided by EP and expect similar results.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al (5,702,717) in view of EP 0092918 in further view of Youxin et al (Journal of Controlled Release (32) 1994, pages 121128).

As set forth above, Cha et al teach thermosensitive biodegradable polymers based on poly (ether-ester) block copolymers for delivery of active agents. EP teaches the use of copolymer blends for various release rates.

The references do not teach the mole ratio of lactic acid to glycolic acid.

Youxin teaches in vivo degradation of thermosensitive triblock copolymers containing bovine serum albumin release. Youxin discloses that the mechanical properties of poly (lactic acid-co-glycolic acid) influence the in-vitro and in-vivo release of proteins from implants. See page 122, third paragraph. Increasing the molar ratio of glycolic acid leads to increase degradation. The reference teaches that the degradation behavior of ABA triblock copolymers influence there physical properties and hence their release properties. See page 125, second column. Lastly, the reference states that depending on the PEO content and lactyl/glycoly ratio, degradation rates can be adjusted. See page 127.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Youxin and manipulate the ratio of glycolic acid to lactic acid of the copolymer. One would be motivated to do so to control the release rate of

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the active agent in the system since this manipulation changes the properties of PGLA such as degradation of the polymer.

Art of Interest

US patent 4,892,903 (Himes) is cited as art of interest since Himes provides the state of the art at the time the invention was made by teachings the combination of two triblock copolymers to provide for a desired polymer product with certain physical features.


Correspondence

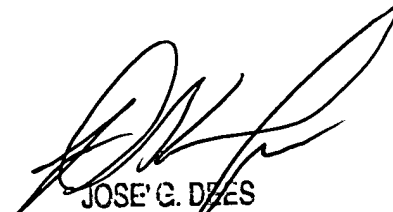
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG


May 5, 2003


JOSE C. DEES
SUPERVISORY PATENT EXAMINER

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